SHOOK, HARDY & BACON LLP
TAMMY B. WEBB (SBN 227593)
Email: tbwebb@shb.com
One Montgomery Tower, Suite 2700
San Francisco, California 94104
Telephone: (415) 544-1904
Facsimile: (415) 391-0281

PATTERSON BELKNAP WEBB & TYLER LLP
STEVEN A. ZALESIN (admitted *pro hac vice*)
Email: sazalesin@pbwt.com
1133 Avenue of the Americas
New York, New York 10036-6710
Telephone: (212) 336-2000
Facsimile: (212) 336-2222

Attorneys for Defendants
THE COCA-COLA COMPANY and COCA-COLA REFRESHMENTS USA, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GEORGE ENGURASOFF and JOSHUA OGDEN, individually and on behalf of all others similarly situated,

Plaintiffs,

vs.

THE COCA-COLA COMPANY and COCA-COLA REFRESHMENTS USA, INC.,

Defendants.

Case No. 3:13-CV-03990-JSW

NOTICE OF MOTION AND MOTION; MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Judge: Hon. Jeffrey S. White

Complaint Filed: August 27, 2013
Hearing Date: February 21, 2014
Hearing Time: 9:00 a.m.
Courtroom: 11

NOTICE OF MOTION AND MOTION

TO PLAINTIFFS AND PLAINTIFFS' ATTORNEY OF RECORD:

PLEASE TAKE NOTICE THAT on February 21, 2014, at 9:00 a.m., or as soon thereafter as this may be heard, in Courtroom 11 of this Court, located at 450 Golden Gate Avenue, San Francisco, CA 94102, before the Honorable Jeffrey S. White, defendants The Coca-Cola Company and Coca-Cola Refreshments USA, Inc. (collectively, "Coca-Cola"), will and hereby do move the Court for an order dismissing the Amended Complaint filed by plaintiffs George Engurasoff and Joshua Ogden.

This motion is made pursuant to Federal Rules of Civil Procedure 12(b)(6), and is based on the following grounds:

1. Plaintiffs' claims are expressly preempted by the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, because they seek to impose requirements for food labeling that are not identical to federal requirements;

2. Plaintiffs' claims are impliedly preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, because they encroach on the exclusive authority of the U.S. Food and Drug Administration ("FDA") to decide how FDA regulations should be interpreted and applied;

3. Plaintiffs' claims fall within the primary jurisdiction of FDA, and raise issues that should be decided by FDA in the first instance; and

4. Plaintiffs' allegations do not state a claim for relief under the California consumer protection statutes.

This motion is based on this notice of motion, the accompanying statement of issues to be decided, the accompanying memorandum of points and authorities, and on such other written and oral argument as may be presented to the Court.

DATE: November 22, 2013

PATTERSON BELKNAP WEBB & TYLER LLP

/s/ Steven A. Zalesin
Steven A. Zalesin

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STATEMENT OF ISSUES

1. Are Plaintiffs' state-law claims, which seek to impose food labeling requirements that do not exist under the FDCA and/or applicable FDA regulations, expressly preempted by the federal Food, Drug and Cosmetic Act?

2. Even if not expressly preempted, are Plaintiffs' claims impliedly preempted because they encroach on FDA's exclusive authority to originally interpret and enforce the FDCA and its implementing regulations?

3. Even if not expressly or impliedly preempted, should Plaintiffs' claims be dismissed under the doctrine of primary jurisdiction, so as to allow FDA—the federal agency with relevant authority and expertise—to decide in the first instance how phosphoric acid, a common food ingredient, should be classified and labeled?

4. Have Plaintiffs stated a claim under California's consumer protection statutes, when they have failed to allege that they read and relied on the specific misrepresentations at issue, and have otherwise failed to plead the elements of their claims?

INTRODUCTION AND SUMMARY OF ARGUMENT

This case is the latest—and, to date, the most outlandish—chapter in an ongoing saga in which a consortium of plaintiffs' lawyers seeks to substitute its judgment for that of the U.S. Food and Drug Administration ("FDA" or the "Agency"), and to persuade the judges of this District to impose labeling requirements for foods and beverages that do not exist under the federal Food, Drug and Cosmetic Act ("FDCA") or the rules and regulations promulgated by FDA.

For more than 125 years, The Coca-Cola Company ("Coca-Cola") has marketed a carbonated cola beverage—known the world over as Coca-Cola® or Coke® ("Coke")—that contains a proprietary combination of ingredients that give the soft drink its unique sensation and taste. One of these ingredients is phosphoric acid, which adds a hint of tartness that balances Coke's otherwise sweet taste.

While the precise formula for Coke is a famously-guarded trade secret, the presence of phosphoric acid in the product is not. Coca-Cola lists phosphoric acid as an ingredient on every container of Coke, as required by the FDCA and its implementing regulations, and has done so for decades. Though Coke had been widely marketed for years before FDA even came into existence, and has enjoyed billions of units of sales in the century since, FDA has never once suggested that there is anything wrong with the way in which Coca-Cola addresses the presence of phosphoric acid in its product labeling or advertising.

Nevertheless, the Plaintiffs in this action allege that Coca-Cola's disclosures concerning phosphoric acid are insufficient—and that the world's most popular beverage is therefore "illegal" and "worthless" under California law. Specifically, Plaintiffs contend that phosphoric acid must be identified on product labels not only by its name, but also as an "artificial flavor" and "chemical preservative." By the same token, Plaintiffs allege that a venerable Coke marketing slogan—"no artificial flavors. no preservatives added. since 1886"—is false because phosphoric acid is, as they see it, *both* an artificial flavor *and* a chemical preservative.

Plaintiffs are just wrong. Their claim is based on their own superficial reading of FDA's regulatory definitions of "artificial flavor" and "chemical preservatives"—definitions that at first blush may appear to encompass phosphoric acid, but in actuality do not. In fact, FDA has

promulgated detailed regulations that list hundreds of ingredients that the Agency considers to be artificial flavors and chemical preservatives, and phosphoric acid is not included in any of these regulations. In other words, FDA has *not* classified phosphoric acid as either an artificial flavor or a chemical preservative, and has *never* required Coca-Cola to identify it as such on product labels.

That is the end of Plaintiffs' case. Decades ago, after considerable debate, Congress decided that food labels should be uniform throughout the Nation, and that one federal agency—FDA—should have sole authority to determine their contents. To implement this policy, Congress expressly preempted the individual states (including state regulators and courts acting under color of state law) from imposing any requirements for the labeling of food that are not *identical* to federal requirements. A requirement that phosphoric acid be labeled as an artificial flavor and/or chemical preservative is a requirement that differs from, and does not exist under, federal law. Plaintiffs' state-law claims seek to impose such a requirement, so they are preempted and must be dismissed. Indeed, for this very reason, courts have repeatedly dismissed similar complaints by private plaintiffs that have sought to reclassify food ingredients and place them into categories that FDA has not.

If Plaintiffs truly believe that phosphoric acid should be reclassified and labeled as an artificial flavor and/or chemical preservative, they are not without a remedy. Procedures exist by which private citizens can petition FDA to alter its regulations, or adopt new rules that differ from those currently in effect. But a party cannot use state law to impose labeling requirements in California—or any other state—that do not already exist under the FDCA. For this reason, and others detailed below, Plaintiffs' Amended Complaint ("AC") must be dismissed.

FACTUAL AND REGULATORY BACKGROUND

A. Coke

Coke has been sold in the United States for more than a century, and is enjoyed by millions of consumers every day. All of the ingredients in Coke are listed on product labels in the manner required by federal law. *See* 21 C.F.R. §§ 101.4(a)(1), 101.4(a)(4). As the labels indicate, Coke

contains carbonated water, high fructose corn syrup, caramel color, phosphoric acid, natural flavors, and caffeine.[1]

Coke's signature taste, which has made it the most popular soft drink in history, is derived from its listed ingredients and its proprietary blend of natural flavors, the identity and exact proportions of which are a renowned trade secret. However, Coca-Cola makes no bones about the role of phosphoric acid in Coke. Its website explains that phosphoric acid "is used in certain soft drinks, including Coca-Cola, to add tartness to the beverage." (AC ¶ 53)[2]

Coca-Cola markets dozens of soft drinks and other beverages aside from Coke, some of which contain artificial flavors (*e.g.*, Powerade® Grape) or chemical preservatives (*e.g.*, Sprite®). Whenever such ingredients are used in its products, Coca-Cola acknowledges their presence on the products' labels exactly as federal law requires. Coke, however, contains no artificial flavors or added chemical preservatives, so no such disclosures are needed.

B. Plaintiffs' Allegations

Plaintiffs are California residents who allege that they purchased Coke products in the past four years that did not disclose the presence of artificial flavors and chemical preservatives on their labels, and/or were marketed with the "no artificial flavors/no preservatives added" slogan. (AC ¶¶ 33-34, 46-48, 49-50) Plaintiffs further allege that phosphoric acid—which, they acknowledge, is listed as an ingredient on every container of Coke—is an artificial flavor and chemical preservative,[3] and must be labeled as such. Plaintiffs therefore assert that Coke is "misbranded" under both the FDCA and California's Sherman Law, which purports to incorporate all FDCA food labeling

[1] The Coke label may be judicially noticed because it is cited throughout Plaintiffs' amended complaint. The Coke labels at issue are attached as Exhibits to the accompanying Request for Judicial Notice ("RJN").

[2] Coca-Cola's statements on this issue have been consistent, to say the least. As early as 1921, Coca-Cola represented in a lawsuit that the function of phosphoric acid in Coke was to "produce the pleasant piquancy which affects the sweetness of the sugar." *Coca-Cola Bottling Co. v. Coca-Cola, Inc.*, 563 F. Supp. 1122, 1131 (D. Del. 1983) (quoting record in *The Coca-Cola Bottling Co. v. The Coca-Cola Co.*, No. 2651 (3d Cir. 1921)).

[3] The Amended Complaint repeatedly alleges that Coke contains "chemical preservatives" (plural). (AC ¶¶ 76, 79, 83-84, 97, 109) Plaintiffs identify no ingredient aside from phosphoric acid that they allege is a chemical preservative.

requirements into state law. (AC ¶¶ 76-77, 80) Plaintiffs thus conclude that the Coke products they purchased were "illegal" and "worthless."[4]

Notably, Plaintiffs cite no legal or regulatory authority for their core contention that phosphoric acid is an artificial flavor or chemical preservative. In particular, Plaintiffs point to no instance in which FDA has taken that position in an enforcement proceeding, or even espoused it in an informal letter to a food or beverage company.[5] Nor do Plaintiffs identify any publication or other statement in which the Agency has concluded that phosphoric acid is an artificial flavor or chemical preservative. Indeed, Plaintiffs point to no label on *any* cola product or other beverage that identifies phosphoric acid in this fashion.[6] Rather, Plaintiffs base their allegations on (1) their own misreading of the regulatory definitions of artificial flavors and chemical preservatives and (2) a few third-party statements on internet websites that supposedly establish that phosphoric acid falls into one or both of these classifications. (AC ¶¶ 53-57)

On this basis and nothing more, Plaintiffs charge that Coca-Cola's labels and advertisements for Coke violate California's Unfair Competition Law ("UCL") (Cal. Bus. and Prof. Code § 17200 *et seq.*), which prohibits, *inter alia*, conduct that is "unlawful" under another statute or regulation. Plaintiffs also assert claims under the False Advertising Law ("FAL") (Cal. Bus. and Prof. Code § 17500 *et. seq.*), the Consumer Legal Remedies Act (Cal. Civ. Code § 1750 *et seq.*) ("CLRA"), and the implied warranty of merchantability (California Commercial Code § 2314(1)). By cobbling together these various state statutes, Plaintiffs seek to impose novel labeling requirements that, as shown below, are vastly different from what FDA has required under the FDCA.

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[4] The Amended Complaint also contains a few stray allegations that Coca-Cola has marketed Coke as embodying the product's "original formula" when, according to Plaintiffs, "unhealthy ingredients" have been added to the formula over time. (AC ¶¶ 13-18, 97) Plaintiffs do not specify when these other ingredients supposedly were added, and do not allege that they relied on the "original formula" representation.

[5] FDA routinely issues "warning" letters to companies whose labels it believes do not comply with applicable regulations or rules. *See* FDA Regulatory Procedures Manual § 4-1. To Coca-Cola's knowledge, FDA has never issued a warning letter to any company that asserts that phosphoric acid is an artificial flavor, chemical preservative or both.

[6] Phosphoric acid is also an ingredient in Pepsi®. Labels for Pepsi, like those for Coke, list phosphoric acid as an ingredient but do not identify it as an artificial flavor or chemical preservative. Plaintiffs' counsel has filed another action in this District asserting that Pepsi, too, is "illegal" and "worthless." *See* 12-cv-1736 (EJD) (N.D. Cal.) (filed April 7, 2012).

C. FDA Labeling Rules

1. General Rules for Food Ingredients, Flavors and Preservatives

As noted above, the FDCA gives FDA sole authority to determine what information is required to appear on food labels throughout the United States. 21 U.S.C. § 343-1(a). Consistent with this statutory mandate, FDA has promulgated detailed regulations concerning the labeling of food ingredients. 21 C.F.R. §§ 101.22; 101.4. These regulations reflect FDA's judgment that consumers are best served by uniform food labels that identify a food's ingredients by name, and list those ingredients in a standardized order.

FDA regulations specify that most food ingredients should be listed in precisely the manner Coca-Cola lists them on Coke—*i.e.*, by their "common or usual name[s]," and "in descending order of predominance by weight." 21 C.F.R. §§ 101.4(a)(1); 101.4(a)(4). This is the default rule that applies to the vast majority of food ingredients. Identification of the *function* of the ingredient is not typically required. Thus, while FDA recognizes more than 30 different functional categories of food ingredients, *see* 21 C.F.R. § 170.3(o)(1)-(32), its regulations specify that ingredients classified in all but a few categories should be identified by name (not function) on product labels.

Artificial flavors and chemical preservatives are exceptions to the general rule. The FDCA requires foods that contain these ingredients to "bear[] labeling stating that fact." 21 U.S.C. § 343(k). Artificial flavors therefore need not be identified by their individual names, but rather should be labeled collectively as "artificial flavors." The regulations specify, in relevant part, that "[t]he label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way: (1) Spice, natural flavor, and artificial flavor may be declared as 'spice,' 'natural flavor,' or 'artificial flavor,' or any combination thereof, as the case may be." 21 C.F.R. § 101.22(h)(1).

Chemical preservatives, in contrast, must be labeled with both their common and usual names and a description of the preservative function they perform:

> A food to which a chemical preservative(s) is added shall . . . bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function e.g., "preservative," "to retard

> spoilage," "a mold inhibitor," "to help protect flavor" or "to promote color retention."

21 C.F.R. § 101.22(j).

Because there are special labeling rules for artificial flavors and chemical preservatives, FDA has adopted detailed regulations that specify which ingredients fall into each of these classifications.

2. Artificial Flavors

FDA regulations define an "artificial flavor" as follows:

> [A]ny substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in §§ 172.515(b) and 182.60 of this chapter except where these are derived from natural sources.

21 C.F.R. § 101.22(a)(1). The cross-referenced sections, §§ 172.515(b) and 182.60, list more than 700 approved or authorized substances that FDA has classified as artificial flavors. These meticulous lists were first promulgated in 1977, when FDA recodified its food regulations to "provid[e] the public and affected industries with regulations that are easy to find, read, and understand." 42 Fed. Reg. 14302, 14302 (Mar. 15, 1977). FDA has processes and procedures in place to supplement its lists when it approves or authorizes new substances as artificial flavors, as it does from time to time. *See*, *e.g.*, 61 Fed. Reg. 14244 (Apr. 1, 1996) (updating regulations to reflect the addition of a chemical commonly used to simulate pineapple flavor).[7]

FDA's regulations concerning artificial flavors reflect the Agency's judgment that not all ingredients that affect the taste of food should be classified as "flavors." Almost every food ingredient has some effect on taste. But FDA considers "flavors" to be a narrower category of ingredients that, when added to food, impart a *characteristic* taste or aroma, such as strawberry or banana. *See* 21 C.F.R. § 170.3(o)(11)-(12) (recognizing that substances that "supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of [their] own" are "flavor enhancers," not flavors or "flavoring agents"); *see also* 21 C.F.R. § 101.22 (defining "artificial flavors" and providing examples such as "strawberry flavor," "banana

[7] FDA also has formal procedures in place for individuals to petition the Agency to rescind or modify a regulation or to reopen the rulemaking process. *See* 21 C.F.R. § 10.30.

flavor" and "vanilla"). In fact, FDA has made clear that many ingredients commonly added to foods for the express purpose of improving taste, such as sugar and salt, are not "flavors" and are not subject to their specialized labeling rules. FDA Compliance Policy Guide § 525.650 (Oct. 1, 1980) (addressing pizza seasonings). Such taste-enhancing ingredients do not qualify as "flavors" because they merely "supplement" or "modify" a food's "original taste and/or aroma" and do not "impart[] a characteristic taste or aroma of [their] own." 21 C.F.R. § 170.3(o)(11). Indeed, FDA has cautioned that "[t]here are many substances whose effect on the taste of food is an important consideration in their use, which are neither 'spices' [n]or 'flavorings' and which *we have consistently refused to sanction being declared as 'spices' or 'flavoring' when used as ingredients*." FDA Compliance Policy Guide § 525.650 (emphasis added). Such ingredients must be listed on food labels by their common and usual names, not as "flavors." 21 C.F.R. § 101.4.

To summarize, FDA considers artificial flavors to be man-made substances that, when added to food, impart a characteristic flavor or original taste, such as cherry or grape. FDA regulations list hundreds of ingredients that are classified as artificial flavors. Those lists purposefully *do not* include *all* ingredients that affect the taste of food.

3. Chemical Preservatives

Just as not all ingredients that affect taste are classified as flavors, not all ingredients that affect a food's tendency to spoil are classified as chemical preservatives. Because of their inherent properties, some food ingredients are more resistant to growth of bacteria or fungi than others. "Chemical preservatives," however, are a special category of substances that, in FDA's judgment, are added to food for the specific purpose of preventing spoilage. In fact, FDA's published definition of chemical preservatives affirmatively excludes a number of common food ingredients that are known to have an incidental preservative effect:

> The term "*chemical preservative*" means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

21 C.F.R. § 101.22(a)(5) (emphasis in original).

FDA regulations further specify that a "food to which a chemical preservative(s) is *added* shall . . . bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its *function* . . . ." 21 C.F.R. § 101.22(j) (emphasis added). This regulatory requirement further evinces FDA's judgment that only ingredients that are specifically *added* to food for their preservative *function* should be labeled as preservatives. Ingredients included for a different purpose, even if they have some incidental preservative effect, instead should be labeled by their common and usual names.

FDA's published regulations identify numerous substances that the Agency has classified as chemical preservatives and has approved or authorized for such use. *See* 21 C.F.R. §§ 182.3013-182.3890; 172.105-172.190; *see also* 42 Fed. Reg. at 14492-95, 14648-49.[8] But even when an ingredient appears on one of these lists, it need not be labeled as a "preservative" unless it is added intentionally to perform that function in the product.

D. Phosphoric Acid

As the foregoing discussion demonstrates, FDA has classified hundreds of food ingredients as artificial flavors, *see* 21 C.F.R. §§ 172.515(b); 182.60, or chemical preservatives, *see* 21 C.F.R. §§ 172.105-172.190; 182.3013-182.3890. Phosphoric acid is a common ingredient that has been used in foods and beverages throughout the past century. Tellingly, however, ***FDA has never classified phosphoric acid as either an artificial flavor or a chemical preservative***. Instead, since FDA's 1977 recodification—the same regulatory pronouncement in which the Agency promulgated lists of more than 700 artificial flavors—FDA has identified phosphoric acid as simply a "multiple purpose GRAS [Generally Recognized as Safe] food substance." 21 C.F.R. § 182.1073.

This is no accidental omission or oversight on FDA's part. Rather, FDA has consistently excluded phosphoric acid from its lists of artificial flavors and preservatives, not only in formal regulations but also informal publications. Notably, for instance, the Agency's "Food Additive

[8] The regulations also recognize a separate category of preservative ingredients called "antimicrobial agents." *See* 21 C.F.R. §§ 170.3(o)(2) (defining antimicrobial agents); 184.1733(c) (classifying sodium benzoate, an ingredient commonly used to preserve soft drinks, as an antimicrobial agent).

Status List"[9] identifies scores of ingredients as either "antimicrobial agents" or "chemical preservatives," but phosphoric acid is not among them. Rather, FDA has repeatedly described the ingredient as simply an "acidifying agent" in numerous foods.[10]

E. The NLEA and Express Preemption

By asking this Court to impose food labeling requirements that are at odds with those of FDA, Plaintiffs seek to establish a regime in which California has different requirements from the rest of the country. That is precisely the condition that led Congress decades ago to preempt states from enacting their own unique food labeling requirements, and to give FDA exclusive authority to standardize food labels nationwide.

For much of the 20th century, most people in the United States consumed food made locally, and food labeling was treated as largely a matter of local (*i.e.*, state-law) concern. But as the food industry modernized and packaged foods sold on a national scale became the norm, the need for uniform federal standards became increasingly clear. Responding to decades of pent up frustration from consumers and manufacturers alike, Congress in 1990 finally recognized that national food labeling standards were overdue. It therefore passed the Nutrition Labeling and Education Act ("NLEA"), which set uniform standards for food labels and prohibited states from enacting (or enforcing any preexisting) non-identical requirements. *See generally* Institute of Medicine, Food Labeling: Toward National Uniformity, National Academy Press (Washington D.C. 1992) ("IOM Report") at 35-54.

Congress's reasons for imposing uniform federal food labeling requirements and displacing all non-identical state requirements are well documented. First, Congress believed that nationwide

[9] http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm091048.htm

[10] *See* 21 C.F.R. §§ 133.123(c)(1) (providing for use of phosphoric acid as an "acidifying agent" in cold-pack and club cheese); 133.124(e)(1) (same for cold-pack cheese food); 133.147(c)(4) (grated American cheese food); 133.169(d)(1) (pasteurized process cheese); 133.173(e)(2) (pasteurized process cheese food); 133.178(b)(3) (pasteurized Neufchatel spread with other foods); 133.179(f)(2) (pasteurized process cheese spread); *see also* 21 C.F.R. §§ 133.129(b)(1)(ii) (providing for use of phosphoric acid to lower pH in dry curd cottage cheese); 131.111(d) (providing for use as an "acidifying ingredient" in acidified milk); 163.110(b)(2) (providing for use as a pH-"[n]eutralizing agent[]" in cacao nibs); 73.85 (noting that phosphoric acid may be used as an "acid[]" to assist caramelization).

uniformity would help consumers "make sense of the confusing array of nutrition labels that confront [them] every time they enter the supermarket." 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Waxman). Second, it would simplify labeling obligations for the food industry. *See* 136 Cong. Rec. S16607-02 (Oct. 24, 1990) (statement of Sen. Hatch) ("[I]t is wrong to . . . burden the manufacturer with the fear of potentially 50 different lawsuits from 50 different State attorneys general, even if similar cases have been dismissed or settled"); 136 Cong. Rec. H5836-01 (1990) (statement of Rep. Bruce) (noting the high cost to food manufacturers "to accommodate any one State with unique food labeling requirements"); 136 Cong. Rec. H5843 (daily ed. July 30, 1990) (statement of Rep. Madigan) (explaining that nationally standardized labeling requirements would "provid[e] the [food and beverage] industry with uniformity of law . . . that will permit them to conduct their business of food distribution in an efficient and cost-effective manner.").

Congress did not act lightly in forcing states out of the business of food labeling regulation. It examined the matter closely, and even postponed the date when certain key provisions of the FDCA would carry preemptive effect. At Congress's direction, the U.S. Institute of Medicine ("IOM") studied the issue in depth, solicited input from consumer groups, industry, and the states, and catalogued the various state laws that the FDCA would displace—including laws relating to the labeling of flavors, colors, and preservatives. *See* IOM Report at 129-133. The IOM noted that some states had more stringent labeling requirements for these ingredients, but concluded that uniform labels would be more helpful to consumers than allowing inconsistent regulations to persist. *Id.* at 133, 136. Only after IOM completed its analysis and concluded that FDA was ready to step into the breach did the NLEA's preemption clause go into full effect. *Id.* at vii-ix.

The NLEA prohibits states from establishing "any requirement for the labeling of a food of the type required by" specific provisions of federal law that is "not identical" to federal requirements—including any requirement concerning "artificial flavoring, artificial coloring, or chemical preservatives," which are governed by 21 U.S.C. § 343(k). 21 U.S.C. § 343-1(a)(3). FDA's published regulations clarify that "not identical" "does not refer to the specific words in the requirement," but instead encompasses any state requirement that "directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a

food container, that: (i) [a]re not imposed by . . . section [341 or 343] of [the FDCA]; or (ii) [d]iffer from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of [the FDCA]." 21 C.F.R. § 100.1(c)(4). Any such non-identical state-law requirement is expressly preempted. *See Carrea v. Dreyer's Grand Ice Cream, Inc.*, 2011 U.S. Dist. LEXIS 6371 (N.D. Cal. Jan. 10, 2011) (White, *J.*), *aff'd*, 475 F. App'x 113, 115 (9th Cir. 2012) (NLEA expressly preempts food labeling requirements beyond those imposed by federal law).

F. FDA's Exclusive Authority to Enforce the FDCA

Even prior to the NLEA's enactment, Congress gave FDA sole authority to enforce the FDCA. *See* 21 U.S.C. § 337(a). In fact, the statute "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).[11] This exclusive enforcement scheme has "major advantages." *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995). FDA has substantial "expertise" that it brings to bear; has the "ability to solicit comment from appropriate sources"; provides "direct representation of the public interest"; and can maintain a "unitary enforcement policy." *Id*.

Because these benefits would be lost if private plaintiffs were allowed to impose their own interpretations of FDCA requirements under state law, courts have consistently held that parties are impliedly preempted from using "state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA." *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290-91 (C.D. Cal. 2008). In other words, the FDCA not only expressly preempts non-identical state labeling requirements, but also impliedly preempts "parallel" state requirements that "exert an extraneous pull" on the uniform enforcement scheme Congress envisioned. *Buckman*, 531 U.S. at 353.

[11] If a state wishes to enforce FDCA requirements using its own police powers, it must notify FDA in advance and give the Agency an opportunity to intervene. *See* FDA, Final Rule: State Enforcement Provisions of the Nutritional Labeling and Education Act of 1990, 58 Fed. Reg. 2457, 2460 (Jan. 6, 1993). States, however, may not seek to enforce the FDCA in any manner "inconsistent with FDA's interpretation of the Act." *Id*.

Plaintiffs here base their claims on the Sherman Law, a California statute that purports to incorporate all FDCA requirements into the law of that state. The Sherman Law contains no private right of action, but California courts have allowed private plaintiffs to enforce the Sherman Law through California's broadly worded Unfair Competition Law. UCL claims, however, are not immune from implied preemption. Indeed, whether a plaintiff's claim arises under the law of California or any other state, the claim is foreclosed whenever a court would be required to determine "preemptively how a federal administrative agency will interpret and enforce its own regulations." *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 928 (9th Cir. 2010).[12]

ARGUMENT

To avoid dismissal under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice"; instead, the plaintiff must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Dismissal is warranted when the plaintiff fails to articulate a viable theory of recovery. *Lucia v. Wells Fargo Bank, N.A.*, 798 F. Supp. 2d 1059, 1072 n.4 (N.D. Cal. 2011).

I. PLAINTIFFS' CLAIMS ARE EXPRESSLY PREEMPTED

Through this action, Plaintiffs seek to use California law to classify a common food ingredient, phosphoric acid, as an artificial flavor and/or chemical preservative. But FDA classifies it as neither, and federal law does not impose the labeling requirements that Plaintiffs would have this Court impose. Plaintiffs' claims are thus squarely barred by NLEA's express preemption clause.

The NLEA prohibits states from imposing any food labeling requirements that are "not identical" to specified categories of requirements under federal law. 21 U.S.C. § 343-1(a)(3). Those preempted categories include requirements "of the type" referenced in 21 U.S.C. § 343(k), which governs the labeling of artificial flavoring and preservatives. It does not matter whether the

[12] Courts outside the Ninth Circuit have reached the same conclusion. *See, e.g., Loreto v. Procter & Gamble*, 515 F. App'x 576, 579 (6th Cir. 2013) (a false advertising claim is barred if it is "in substance (even if not in form) a claim for violating the FDCA").

requirements Plaintiffs seek to establish would be consistent with the FDCA, or would arguably complement its purpose. If the proposed requirements do not already exist under federal law, they are preempted. 21 C.F.R. § 100.1(c)(4); *Turek v. General Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011) ("consistency is not the test; identity is"). Plaintiffs' state-law claims must therefore be dismissed.

A. FDA Does Not Classify Phosphoric Acid as an Artificial Flavor

Plaintiffs' claims proceed from the premise that every ingredient that affects the taste of a food is a "flavor," and that if such an ingredient is man-made, it must be labeled as an "artificial flavor." (AC ¶ 58) Neither of these assumptions is correct. In fact, they contradict FDA's entire approach and considered judgment as to how food ingredients should be classified and labeled.

1. "Flavors" Impart a "Characteristic" Flavor or Aroma

Many—if not substantially all—ingredients added to food will have an effect on its taste. But FDA has made clear that not every ingredient that affects taste is a "flavor." FDA recognizes more than 30 different categories of food ingredients, most of which impact the taste of the finished product. 21 C.F.R. § 170.3(o)(1)-(32). But FDA has classified only a small subset of ingredients as "flavoring agents" or flavors. An ingredient is properly labeled as a "flavor" only if it "impart[s] a characteristic taste or aroma of its own"—not if it simply enhances or modifies the food's "original taste." *See* 21 C.F.R. § 170.3(o)(11)-(12).

There is good reason for FDA's approach. As noted above, ingredients properly classified as "flavors" are declared generically as a group on product labels, not individually by their common names. If Plaintiffs were correct that any ingredient that impacts taste should be labeled as a "flavor," then thousands of food additives that are currently required to be listed by name could be identified simply as "flavors." Indeed, rather than provide a full list of their actual ingredients, the labels for most beverage products would simply read "water, natural and artificial flavors." FDA has explicitly rejected such attempts to circumvent the FDCA's requirement that most ingredients be identified on food labels by their common and usual names. *See* FDA Compliance Policy Guide § 525.650 ("There are many substances whose effect on the taste of food is an important consideration

in their use, which are neither 'spices' nor 'flavorings' and which we have consistently refused to sanction being described as 'spices' or 'flavorings' when used as ingredients.").

In fact, there are countless examples of food ingredients and additives that have a pronounced effect on taste, but are not considered "flavors" by FDA. Sweeteners such as sugar, aspartame and high fructose corn syrup all contribute markedly to the taste of foods and beverages, but are not classified, and may not be labeled, as "flavors." Salt impacts the taste of potato chips, but must be listed as "salt"—not as a "flavor." The examples are endless, but the point is the same: taste and flavor are *not* coextensive, and FDA rules and regulations recognize as much. Plaintiffs' bid to eliminate the distinction between the two not only is ill-conceived, it is preempted as a matter of law for the simple reason that it differs from FDA's classification scheme.

2. Phosphoric Acid Is Not an "Artificial Flavor"

Plaintiffs' next leap is to assume that if an ingredient that affects taste is man-made, it must be disclosed as an "artificial flavor." But here, too, Plaintiffs' theory ignores FDA's pronouncements on the subject. FDA has promulgated regulations that list more than 700 ingredients the Agency deems "artificial flavors." *See* 21 C.F.R. §§ 172.515(b), 182.60; *see also* 21 C.F.R. § 101.22(a)(1) (cross-referencing lists). Despite its longstanding use as a common food ingredient, phosphoric acid does not appear on FDA's lists. Indeed, FDA has explicitly identified tricalcium phosphate—the starting material from which phosphoric acid is made—as an "example[]" of the type of ingredient "whose effect on the taste of food is an important consideration" in its use, but whose labeling as a "flavoring" FDA has "consistently refused to sanction." FDA Compliance Policy Guide § 525.650.

Courts in this Circuit have repeatedly held that private attempts to re-classify ingredients as "artificial flavors" when FDA has not done so are expressly preempted by the NLEA. In *Viggiano v. Hansen Natural Corp.*, 2013 U.S. Dist. LEXIS 70003, at *27 (C.D. Cal. May 13, 2013), for instance, the court dismissed a complaint alleging that a soda manufacturer had falsely represented its products as containing "all natural flavors" when they contained the artificial sweeteners sucralose and ace-k. The court concluded that the plaintiffs' state-law claims were expressly preempted because, under FDA regulations, "neither sucralose nor ace-k are 'flavors,' as they do not give the

product an original taste . . . . Also, and perhaps most significantly, neither substance appears on the list of artificial flavors promulgated by the FDA." *Id.* Plaintiffs here make a nearly-identical attempt to reclassify phosphoric acid as an "artificial flavor" contrary to FDA's judgment and regulatory scheme. Their claim should similarly be rejected.

Likewise, in *Lam v. General Mills, Inc.*, 859 F. Supp. 2d 1097, 1102 (N.D. Cal. 2012), the plaintiffs challenged affirmative claims on fruit-snack labeling that the snacks were "naturally flavored." In fact, the snacks contained a number of synthetic ingredients, including malic acid—a man-made compound that, not unlike the phosphoric acid in Coke, adds tartness to foods whose taste is predominantly sweet. The court dismissed the plaintiffs' claims as expressly preempted because the products' only characterizing fruit flavor (strawberry) was undisputedly natural, and because the synthetic ingredients that affected the taste of the product were not "flavors." *Lam*, 859 F. Supp. 2d at 1102-03 (noting that plaintiffs' real point was "the products' *ingredients*, not their *flavors*, are unnatural.") (emphasis added); *see also Ivie v. Kraft Foods Global, Inc.*, 2013 U.S. Dist. LEXIS 93940, at *14 (N.D. Cal. June 28, 2013) ("While [potassium citrate and sodium citrate] may be artificial ingredients, nothing in the FDA regulations suggests that these ingredients are flavors, artificial or otherwise . . . Neither product . . . is included in the FDA's list of artificial flavors"); *Pelayo v. Nestle USA, Inc.*, 2013 U.S. Dist. LEXIS 154434, at *13 (C.D. Cal. Oct. 25, 2013) (dismissing complaint where "Plaintiff fail[ed] to allege that any of the Challenged Ingredients are present in the product specifically as an added 'flavor.'").[13]

Notably, the courts in several of these cases dismissed a complaint challenging an affirmative statement that, like Coca-Cola's slogan for Coke, indicated that the product contained no artificial flavors. *Lam*, 859 F. Supp. 2d at 1102; *Viggiano*, 2013 U.S. Dist. LEXIS 70003, at *18; *Ivie*, 2013 U.S. Dist. LEXIS 93940, at *14. As these rulings reflect, there can be only one definition of "artificial flavor" for purposes of product labeling and marketing, and that definition is the one

[13] Plaintiffs suggest that, because phosphoric acid is not a "natural flavor," it must necessarily be an "artificial flavor." (AC ¶¶ 64-67) That is not the operative test. As shown above, in order for an ingredient to be classified as either an "artificial flavor" or "natural flavor," it must first be a *flavor*—that is, an ingredient that imparts an original taste or aroma of its own. Phosphoric acid, like thousands of other man-made food ingredients, does no such thing.

promulgated by FDA. Accordingly, not only is Plaintiffs' challenge to Coca-Cola's alleged failure to disclose the presence of artificial flavors on its labels preempted, but so too is their attack on Coca-Cola's "no artificial flavors" slogan. Both claims must be dismissed.

In sum, FDA has taken the clear position that phosphoric acid is not an "artificial flavor." For that reason, Coca-Cola has never labeled phosphoric acid as an artificial flavor, and neither (to Coca-Cola's knowledge) has any other soft-drink manufacturer. FDA has never registered any objection to this state of affairs, despite having had every opportunity to mandate a change to this practice, if it saw fit. Because Plaintiffs' state-law claims would require that phosphoric acid be designated as an artificial flavor in contravention of FDA's stance on the subject, Plaintiffs' claims are expressly preempted under the NLEA.

B. FDA Does Not Classify Phosphoric Acid as a Preservative

Like their claim about "artificial flavors," Plaintiffs' contention that phosphoric acid must be labeled as a "chemical preservative" is built on a faulty assumption. Plaintiffs presume that any ingredient that has the effect of lowering the pH of a food product, thereby making it less hospitable for bacteria to grow, is necessarily a "preservative."[14] Were Plaintiffs correct, then every acidic ingredient added to a food—including ingredients like citric acid, malic acid, and even lemon juice,[15] which are commonly added for their effect on taste—would have to be labeled as "preservatives," regardless of whether they were added to the product to serve a preservative function.

That is not at all the way that FDA approaches the issue. Rather than focusing on the incidental preservative effect that myriad ingredients *may* have in a product, FDA defines chemical preservatives as ingredients that are intentionally "added" to foods specifically to provide a preservative function. *See* 21 C.F.R. § 101.22 (a)(5) and (j). To this end, FDA's regulations on the labeling of preservatives require manufacturers to include on the label the name of the ingredient and

[14] More specifically, Plaintiffs' claim appears to be that, because it is an "acid," phosphoric acid necessarily must be an "acidulant," a class of ingredients defined on Coca-Cola's "Beverage Institute for Health and Wellness" website as compounds that can help "reduce the growth of microorganisms (i.e., protect the food from spoiling)." Plaintiffs point to this innocuous statement about "acidulants" as proof that phosphoric acid is a chemical preservative that must be labeled as such. (*See* AC ¶ 54)

[15] FDA classifies none of these ingredients as a preservative. *See, e.g.,* 21 C.F.R. §§ 184.1033 (citric acid); 184.1069 (malic acid).

"a separate description of its function, e.g., 'preservative', 'to retard spoilage', 'a mold inhibitor', 'to help protect flavor' or 'to promote color retention'." 21 C.F.R. § 101.22(j). If an ingredient is not added to a product to serve a preservative function, it is not considered a preservative for purposes of the product's label.

FDA regulations are clear on this point. When FDA first defined "chemical preservative" in 1938, it excluded from the definition "common salt, sugars, vinegars, spices, or oils extracted [from those substances]," reflecting the principle that if an ingredient is added to food for its effect on taste, an incidental preservative effect does not make that ingredient a "preservative" under the FDCA. 3 Fed. Reg. 3161 (Dec. 28, 1938). This same language is present in the current regulation. *See* 21 C.F.R. § 101.22(a)(5); *see also* FDA Compliance Policy Guide § 562.600 (explaining that labeling must indicate whether a food ingredient is "added as a preservative").

FDA provides further guidance on this subject in the form of regulations that list the ingredients the Agency considers to be preservatives. 21 C.F.R. §§ 182.3013-182.3890; 172.105-172.190.[16] These regulations delineate the substances used by the food industry that, according to FDA, are added to foods for their preservative effects and should be labeled as such. Phosphoric acid is absent from the lists. FDA likewise has not deemed phosphoric acid a "preservative" in its informal publications. *See, e.g.*, "Food Additive Status List."[17] Further, FDA has opted not to classify phosphoric acid as an "antimicrobial agent," *i.e.*, a "[s]ubstance[] used to preserve food by preventing growth of microorganisms and subsequent spoilage," 21 C.F.R. § 170.3(o)(2), although it has affixed that label to some other acidic ingredients that are commonly used to preserve soft drinks. *See* 21 C.F.R. § 184.1733(c) (classifying sodium benzoate as an antimicrobial agent); 21 C.F.R. § 184.1021(c) (same for benzoic acid). The fact that FDA has recognized the preservative function of other common soft-drink ingredients but not phosphoric acid—an ingredient that

[16] Although 21 C.F.R. § 101.22(a)(5) does not cross-reference these lists, FDA relies on them in its enforcement activities related to the labeling of preservatives. *See, e.g.*, FDA Warning Letter to Bagels Forever, Inc., July 22, 2011 ("Your product . . . contains potassium sorbate, which is *listed in 21 C.F.R. § 182.3640 as a chemical preservative*; therefore, your product may not make the claim[] . . . 'No Preservatives.'") (emphasis added).

[17] http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm091048.htm

virtually all cola producers use but (as far as Coca-Cola is aware) never label as a preservative—reflects FDA's considered judgment that phosphoric acid is not properly classified as a preservative, and should not be labeled as such.

Given the foregoing, Plaintiffs' claim that Coca-Cola must label phosphoric acid as a "preservative" is squarely preempted. FDA has exercised its judgment in identifying ingredients that it considers to be preservatives. FDA has also made clear that an ingredient with merely an incidental preservative effect should not be labeled as a preservative if it is added to a food to serve a different function. Coca-Cola has scrupulously followed FDA's rules in this regard in *not* listing phosphoric acid as a preservative on the label for Coke. Because Plaintiffs' alternative labeling scheme is contrary to the regulations, guidance, and other pronouncements that FDA has provided on the issue, their claims are expressly preempted and must be dismissed. *See Carrea v. Dreyer's Grand Ice Cream, Inc.*, 2011 U.S. Dist. LEXIS 6371 (N.D. Cal. Jan. 10, 2011) (White, *J.*), at *5-6, *aff'd*, 475 F. App'x 113, 115 (9th Cir. 2012) (claim that sought to use state law to impose labeling requirements for trans fat contrary to FDA regulations held expressly preempted); *see also Perez v. Nidek Co.*, 711 F.3d 1109, 1118-19 (9th Cir. 2013) (claim expressly preempted where plaintiff "effectively [sought] to write in a new provision to the FDCA").[18]

II. PLAINTIFFS' CLAIMS ARE IMPLIEDLY PREEMPTED

Even if there were some doubt as to how FDA classifies phosphoric acid, Plaintiffs' claims would be barred by the doctrine of implied conflict preemption. Implied preemption bars state-law claims that would "exert an extraneous pull" on the uniform enforcement scheme established by Congress, which entrusts a single federal agency—FDA—with responsibility for interpreting and enforcing the FDCA's requirements. *Buckman*, 531 U.S. at 353. Implied preemption sweeps more broadly than express preemption. Even when a state-law claim on its face appears "identical" to federal law, implied preemption bars the claim if it "would require a court to interpret ambiguous

[18] The Amended Complaint points to a website not operated by Coca-Cola that provides the following glossary entry for phosphoric acid: "This flavoring agent in soft drinks is a preservative that provides tartness." (AC ¶ 57) This ambiguous and self-contradictory statement does not, and cannot, override FDA's regulatory determination that phosphoric acid is not a chemical preservative and should not be classified as such.

FDA regulations," *POM Wonderful LLC v. Coca-Cola, Co.*, 679 F.3d 1170, 1178 (9th Cir. 2012), or to determine "preemptively how [FDA] will interpret and enforce its own regulations," *PhotoMedex*, 601 F.3d at 928.[19]

Plaintiffs' claims in this case would not just exert a "pull" the FDCA's enforcement scheme, they would usurp FDA's authority entirely. FDA has never determined that phosphoric acid is an artificial flavor or a chemical preservative, notwithstanding the fact that hundreds of foods and beverages, including Coke, have used phosphoric acid as an ingredient and disclosed it on their labels for decades. As such, Plaintiffs are asking the Court to undertake the reclassification of phosphoric acid—and to divine FDA's position on whether phosphoric acid is an artificial flavor, a chemical preservative, or both—without any guidance from FDA as to how, or even whether, FDA's regulatory definitions apply.

The Ninth Circuit's decision in *PhotoMedex v. Irwin* makes clear that such claims are barred. In that case, *PhotoMedex* asserted that a competitor, Ra Medical, was marketing a medical device that was "significantly" different from any device that FDA had previously approved, and that Ra Medical should therefore have sought *de novo* review of its device by FDA before offering it for sale. PhotoMedex initially complained to FDA about Ra Medical's device and "urg[ed]" FDA "to take . . . enforcement action," but FDA had not done so. *Id*. at 926-28. PhotoMedex then sued Ra Medical over its alleged FDCA violations, asserting claims under federal and California unfair competition laws.[20]

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[19] The fact that a statute contains an express preemption provision has no bearing on whether a claim is impliedly preempted. As the U.S. Supreme Court has made clear, such a clause "does not bar the ordinary working of conflict pre-emption principles or impose a 'special burden' that would make it more difficult to establish [implied] preemption of laws falling outside the clause." *Arizona v. United States*, 132 S. Ct. 2492, 2505 (2012); *Buckman*, 531 U.S. at 352 (same). Indeed, the Ninth Circuit recently reaffirmed that, notwithstanding the FDCA's express preemption provisions, the FDCA impliedly preempts state-law claims that usurp the FDA's authority to interpret and apply the requirements of federal law. *See Perez*, 711 F.3d at 1118-19 (explaining the "narrow gap" left between express and implied preemption under the FDCA).

[20] The *PhotoMedex* opinion referred chiefly to PhotoMedex's Lanham Act claim. However, the court's *holding* affirmed the dismissal of the UCL claim on the same grounds, 601 F.3d at 930-31 & n.7, and its reasoning depended heavily on Supreme Court precedent addressing implied preemption of state law, *id.* at 924 (citing *Buckman*, 531 U.S. at 344).

The Ninth Circuit held that PhotoMedex's claims were barred because "[v]alidating PhotoMedex's position would require us to usurp [the FDA's] responsibility for interpreting and enforcing potentially ambiguous regulations." *Id*. at 930 (citation and quotation marks omitted). PhotoMedex was "not permitted to circumvent" FDA by seeking to "prove that [Ra] violated the FDCA" when FDA had never "reach[ed] that conclusion." *Id*. at 928. Rather, "the appropriate forum for PhotoMedex's complaints" was "the responsible regulatory agency"—that is, FDA. *Id*. at 929.

In the years since *PhotoMedex* was decided, the Ninth Circuit has repeatedly applied its holding to bar claims that would usurp FDA's authority to determine how the requirements of the FDCA should be interpreted and enforced. *See, e.g.*, *POM Wonderful*, 679 F.3d at 1178 (holding that a private plaintiff's false advertising claim is foreclosed "when it would require a court to interpret ambiguous FDA regulations" and noting that a "court [may not] act" on issues that require agency expertise "when the FDA has not").[21] Most recently, in *Perez v. Nidek Co.*, the Ninth Circuit held that a plaintiff's California state-law claims were impliedly preempted because, *inter alia*, they would have required a court to decide whether the defendant had violated the FDCA before FDA had made its own determination. 711 F.3d at 1119-20.

The Ninth Circuit's holdings in *PhotoMedex*, *POM Wonderful*, and *Perez* are all applicable here. Congress has given FDA sole authority to promulgate regulations and enforce the FDCA's artificial flavor and chemical preservative requirements, and FDA has classified hundreds of food ingredients into those categories—but not phosphoric acid. Plaintiffs here have no greater right than the plaintiffs in *PhotoMedex*, *POM Wonderful*, or *Perez* to "bypass the FDA," *PhotoMedex*, 601 F.3d at 929, and ask a court find that Coca-Cola has violated FDCA requirements in circumstances where FDA has not.[22] Rather, the "'appropriate forum for [Plaintiffs'] complaints is the [FDA].'"

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[21] The Ninth Circuit's decision in *POM Wonderful* affirmed the dismissal of the plaintiff's Lanham Act claim. On remand, however, the district court held that the Ninth Circuit's reasoning applied with equal force to the plaintiff's California unfair competition claims and dismissed those claims as well. *See POM Wonderful LLC v. Coca Cola Co.*, 2013 U.S. Dist. LEXIS 33501, at *14 (C.D. Cal. Feb. 13, 2013).

[22] Plaintiffs will likely invoke the California Supreme Court's decision in *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077 (2008), which rejected an implied-preemption defense to a UCL claim involving alleged violations of California's Sherman Law. But the facts of *In re Salmon* are readily

POM Wonderful, 679 F.3d at 1178; *see also Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) (claims barred because they required court to "determine preemptively how a federal administrative agency will interpret and enforce its own regulations").

III. PLAINTIFFS' CLAIMS FALL WITHIN FDA'S PRIMARY JURISDICTION

Even if Plaintiffs' claims were not preempted (which they are), the Court should nevertheless decline to adjudicate whether phosphoric acid is an artificial flavor and/or chemical preservative on primary jurisdiction grounds. Primary jurisdiction permits courts to dismiss "an otherwise cognizable claim" when, as here, it "implicates technical and policy questions" that a regulatory agency should resolve in the first instance. *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). The doctrine is necessary to avoid ensnaring courts in matters within an agency's jurisdiction, especially when a claim "requires resolution of an issue of first impression," *id.*, and "expertise or uniformity in administration," *Syntek Semiconductor Co., Ltd. v. Microchip Tech., Inc.*, 307 F.3d 775, 780, 781 (9th Cir. 2002) (internal quotation marks omitted).

Here, all of the factors relevant to primary jurisdiction weigh in favor of dismissal. Plaintiffs' claims would require the Court to resolve an issue that is squarely within FDA's jurisdiction. 21 C.F.R. § 10.25(b) (FDA has "primary jurisdiction" to make "the initial determination on issues within its statutory mandate."). The issue implicates FDA's expertise and potentially impacts the labeling of thousands of products nationwide. *See POM Wonderful*, 679 F.3d at 1178 (noting that courts "lack the FDA's expertise in guarding against deception in the context of juice beverage labeling"). And FDA has *never* applied the regulatory definitions of artificial flavors and chemical preservatives in the manner that Plaintiffs here advance, so the Court at best would be required to "decide an issue committed to the FDA's expertise without a clear indication of how FDA would view the issue." *Hood v. Wholesoy & Co.*, 2013 U.S. Dist. LEXIS 97836, at *13 (N.D. Cal. July 12, 2013). In these circumstances, dismissal on primary jurisdiction grounds is clearly

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distinguishable. Plaintiffs there alleged that defendants had failed to abide by an FDCA requirement concerning the disclosure of dyes that FDA had expressly classified as artificial colorants. In other words, the *Salmon* plaintiffs sought to enforce a state-law requirement that already existed under federal law. Here the exact opposite is true: FDA *has not* classified phosphoric acid as an artificial flavor or chemical preservative, so there is no federal requirement that it be labeled it as such.

warranted. *Astiana v. Hain Celestial Grp., Inc.*, 905 F. Supp. 2d 1013, 1016 (N.D. Cal. 2012) (dismissing complaint where the disputed "labeling [was] governed by the FDCA and by extensive FDA regulations" that were "silent" as to central issue in the case); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc*., 586 F.3d 500, 508-10 (7th Cir. 2009) (Posner, J.) (FDA "should be given a chance to opine on the proper labeling" before a suit is filed because the Agency "has more experience with consumers' understanding of labels than judges").

IV. PLAINTIFFS' CLAIMS ARE INADEQUATELY PLED

As set forth above, Plaintiffs' claims are barred by preemption and primary jurisdiction, and no amendment could cure those defects. But Plaintiffs' claims are also inadequately pled. The Amended Complaint fails in various respects to (1) allege reliance as required by California's consumer protection statutes; (2) set forth a viable claim against Coca-Cola's statements concerning Coke's "original formula"; or (3) state a claim for breach of the implied warranty of merchantability.

A. Plaintiffs Fail to Plead Reliance Under the UCL, the FAL, or the CLRA

The Amended Complaint is deficient in that it does not allege that Plaintiffs relied on Coca-Cola's supposed misrepresentations and omissions. In order to make out a claim under the UCL or FAL based on misrepresentations in labeling or advertising, a plaintiff must "demonstrate actual reliance on the allegedly deceptive or misleading statements," and must allege facts that "show that the misrepresentation was an immediate cause of the injury-producing conduct." *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 326-27 (2011) (internal quotation marks omitted). The CLRA similarly requires a plaintiff to allege that "the omission or affirmative misrepresentation contained within an allegedly misleading statement . . . [was] material to the consumer's evaluation of a product." *Brod v. Sioux Honey Ass'n*, 927 F. Supp. 2d 811, 830 (N.D. Cal. 2013). Reliance is thus necessary to establish standing to assert claims under these statutes. *Kwikset*, 51 Cal. 4th at 323-23.

Moreover, because Plaintiffs' claims sound in fraud, their allegations—including those of reliance—must satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). *Vess v. Ciba-Geigy Corp.*, 317 F.3d 1097, 1103-04 (9th Cir. 2003) (where "claim is . . . grounded in fraud or [] sound[s] in fraud, [] the pleading of that claim as a whole must satisfy the particularity requirement of Rule 9(b)."") (internal quotation marks omitted). Under Rule 9(b), "general allegations" regarding

"how [plaintiff] was made aware of [defendant's] representations" do not suffice for purposes of pleading reliance. *Briseno v. Conagra Foods, Inc.*, 2011 U.S. Dist. LEXIS 154750, at *29-41 (C.D. Cal. Nov. 23, 2011).

Here, Plaintiffs allege only in the vaguest terms that they "relied on the Coca-Cola labels" (AC ¶¶ 116-118), and nowhere claim that they relied on specific statements or omissions regarding artificial flavors or preservatives. This is insufficient: "A plaintiff is not permitted to support a claim alleging misleading product packaging with statements that he never read or relied upon when making his purchase," or to plead a claim of reliance with "vague reference[s]" to a marketing campaign that is claimed to be misleading. *Bronson v. Johnson & Johnson, Inc.*, 2013 U.S. Dist. LEXIS 54029, at *8 (N.D. Cal. Apr. 16, 2013); *see also Dvora v. General Mills, Inc.*, 2011 U.S. Dist. LEXIS 55513, at *8 (C.D. Cal. May 16, 2011) (plaintiff must specifically allege that he read and relied on the challenged label statements).

Plaintiffs cannot avoid the requirement that they plead reliance by contending that the Coke they purchased was "misbranded," that it was therefore "legally worthless," and that they would not have purchased it had they known as much. (AC ¶ 95, 112-14, 145-149) That theory has been rejected by several courts in this Circuit. In *Wilson v. Frito-Lay North America, Inc.*, 2013 U.S. Dist. LEXIS 153136, at *22-23 (N.D. Cal. Oct. 24, 2013), for example, the court held that "plaintiffs must show that they lost money or property because of reliance on an allegedly unlawful practice," and that "alleged violation of labeling laws alone[,] separate from any alleged fraud or deception connected with Plaintiffs' reliance or injury," was insufficient to support a UCL claim. *Id*. at *24; *see also In re Actimmune Mktg. Litig.*, 2010 U.S. Dist. LEXIS 90480, at *8 (N.D. Cal. Aug. 31, 2010), *aff'd*, 464 F. App'x 651 (9th Cir. 2011) (plaintiffs must plead reliance on the complained-of statements, even if UCL claim arises under the statute's "unlawfulness" prong).

B. Plaintiffs' "Original Formula" Claim Fails

The Amended Complaint includes two throw-away references to Coca-Cola's "original formula." (AC ¶ 16, 97) Neither of these averments appeared in Plaintiffs' original complaint; they were added to the Amended Complaint for the apparent purpose of providing some sensational flare to Plaintiffs' threadbare pleading. But Plaintiffs "original formula" allegations fail to state a claim

for at least two reasons. *First*, Plaintiffs do not allege that they actually saw the "original formula" claim prior to purchasing Coke, or that it played any role in their purchase decisions. As detailed above, such failure to plead reliance with specificity requires dismissal.

Second, Plaintiffs' assertion that the phrase "original formula" implies that Coke is healthy and free of artificial flavors and chemical preservatives (*see* AC ¶ 16) is virtually identical to one that this Court rejected in *Carrea v. Dreyer's Grand Ice Cream*. The *Carrea* plaintiff alleged that "Original" claims on labeling for ice cream implied that the dessert was healthy and free of dangerous trans fats. This Court held that such a tortured interpretation of "Original" was implausible as a matter of law, and the Ninth Circuit affirmed the dismissal of the complaint on appeal. *See Carrea*, 475 F. App'x at 115 ("[I]t strains credulity to claim that a reasonable consumer would be misled to think that an ice cream . . . is healthier than its competitors simply by virtue of these 'Original' and 'Classic' descriptors."). The outcome can be no different here.

C. Plaintiffs Have No Implied Warranty Claim

Plaintiffs' Amended Complaint concludes with a claim for breach of the implied warrant of merchantability. This claim suffers from the same fatal defect that infects Plaintiffs' entire case.

Plaintiffs do not claim that there was anything wrong with the Coke they purchased, or that they did not consume or enjoy it. On the contrary, Plaintiffs allege that they bought Coke repeatedly on multiple occasions, only to realize later that the product was legally "worthless." California courts have consistently held that this kind of subjective remorse cannot sustain a claim for breach of the implied warranty of merchantability, unless the product actually "did not possess even the most basic degree of fitness for ordinary use." *Viggiano*, 2013 U.S. Dist. LEXIS 70003, at *48; *Brod*, 927 F. Supp. 2d at 831 (same).

Plaintiffs here allege nothing of the sort. Coke is not only "merchantable," it is precisely what it claims to be: a refreshing, great-tasting beverage enjoyed by millions of consumers around the globe every day. Plaintiffs' inability to allege otherwise requires dismissal of their implied warranty claim, along with the rest of their case.

CONCLUSION

Coke is, and always has been, labeled and marketed in accordance with the applicable provisions of the FDCA and implementing regulations established by FDA. Plaintiffs seek to use California state law to impose new labeling rules that do not exist under federal law. Their claims are therefore preempted, and may not proceed. The Amended Complaint should be dismissed, in its entirety, with prejudice.

DATE: November 22, 2013

Respectfully submitted,

PATTERSON BELKNAP WEBB & TYLER LLP

/s/ Steven A. Zalesin
Steven A. Zalesin (admitted *pro hac vice*)
Email: sazalesin@pbwt.com
Sarah E. Zgliniec (admitted *pro hac vice*)
Travis J. Tu (admitted *pro hac vice*)
Jane M. Metcalf (admitted *pro hac vice*)
1133 Avenue of the Americas
New York, New York 10036
Telephone: (212) 336-2000
Facsimile: (212) 336-2222

SHOOK, HARDY & BACON LLP
Tammy B. Webb (SBN 227593)
Email: tbwebb@shb.com
One Montgomery Tower, Suite 2700
San Francisco, California 94104
Telephone: (415) 544-1904
Facsimile: (415) 391-0281

Attorneys for Defendants